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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,070	02/26/2000	Merrill A Biel	22272-14	8621

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3739	20

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/514,070	Beck
Examiner	Group Art Unit
D. Shay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on November 7, 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 50 - 53 + 55-59 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 50-53 + 55-59 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al combination with Singer et al. Lai et al teach a method of cellular disruption using photosensitizing agent (column 6, line 36 to column 19, lines 67). Singer et al teach that at concentrations of SDS below that at which complete cell lysis occurs, cell permeability is greatly increased and that SDS is used as a delivery aid in pharmaceuticals. It would have been obvious to the artisan of ordinary skill to employ SDS in the method of Lai et al, since this would aid the delivery of the pharmaceutical agent and to employ an SDS concentration as claimed, since Singer et al give no minimum concentration below which the "cell permeability is greatly increased" as this happens at any concentration below that at which cell lysis occurs, as taught by Singer et al, and since this would reduce the extent to which non-cancerous cells are affected.

Claims 50-53, 55, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al, Singer et al, and Williams et al. Swartz et al teaches a method such as claimed except the use of a surfactant (please note the absence of teaching of the use of a surfactant necessarily includes the absence of limitations predicated on the use of surfactant e.g. the use of a particular concentration of surfactant) and gives few particulars regarding light application. Asculai et al teach the usefulness of surfactants for inactivating viruses. Singer et al teach that SDS permiabilizes membranes greatly at concentrations below that at which total lysis occurs. Williams et al teach controlling gel properties through the use of surfactants. It would have been obvious to the artisan of ordinary skill to employ a surfactant in the method of Swartz et al since this would help inactivate the virus, as taught by Asculai et al as well as to control gel properties, as taught by Williams et al;

and to use the claimed concentrations, since these will permiabilize the membranes by attacking the lipids therein, as taught by Singer et al, thus producing a method such as claimed.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al, Swinger et al, and Williams et al as applied to claims 50-53, 55, and 57-59 above, and further in combination with Lai et al. Lai et al teach light dosages and dosage rates as claimed for activating a photosensitizer. It would have been obvious to the artisan of ordinary skill to employ the dosage and dosage rate as taught by Lai et al, since these will activate the photosensitizer and since Swartz et al supply no particular dosage or dosage rates, thus producing a method such as claimed.

Applicant argues that Lai et al do not employ the surfactant mixtures in the in vivo experiments. The rejections have been altered to remedy this deficiency.

Applicant argues that no combination of the references applied to claims 55-59 teach or suggest the claimed concentration range of SDS, citing In re *Royka*. The examiner must respectfully disagree. The teachings of Singer et al expressly teach that concentrations below that causing complete cell lysis increase membrane permeability. This is a clear teaching of using concentrations such as those claimed. If applicant is aware of a teaching in Swinger et al which specifically discusses avoiding the claimed concentration range the examiner respectfully requests that such passage be specifically pointed out an applicant's response hereto. Also applicants' claim 65 requiring merely a concentration of greater than .003% of SDS is clear evidence of the non-criticality of this range.

Regarding the alleged lack of motivation of combining of Asculai with Williams et al, the teaching of the use of nonionic surfactants by Asculai is noted, however, Williams et al exclude

no particular class of surfactants, thus it is unclear why applicant feels these teachings cannot be combined. A more detailed explanation of the mitigating teachings in Williams et al must be provided before the examiner can provide a more through analysis of applicants assertion in this regard.

Applicant continues asserting that there is no motivation to modify Asculai to use SDS. The examiner respectfully notes that the rejection involving Asculai makes no mention whatsoever of modifying this reference. Thus this argument is not germane to the applied rejections and as such is not persuasive.

Applicant's arguments filed November 7, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Applicant's arguments with respect to claims 50-53 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Shay/Dl

January 28, 2004